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Award Number: W81XWH-04-1-0768

TITLE: Androgen Replacement as Treatment for Hormone Refractory Prostate Cancer

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT
This grant funded planning activities for initiation of a randomized phase II trial to study androgen replacement in early phase hormone refractory prostate cancer. A grant was completed and submitted to the DOD. A clinical protocol was completed and submitted to the IRB. All regulatory and collaborative agreements were completed except for finalization of drug delivery process with the pharmaceutical collaborator when it was announced that the clinical trial grant was not funded.

15. SUBJECT TERMS
Phase II, androgen replacement, hormone refractory, quality of life

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Table of Contents

DOD Planning Annual Report

Introduction: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.

Body:
This planning grant was awarded to finalize the plans and protocol for a randomized phase II trial of testosterone replacement in men with early hormone refractory prostate cancer. The vast majority of the planned development was actually carried out and a final clinical trial grant was submitted on 12/7/04. Specifically cognitive testing tools were finalized, a hand grip dynamometer was obtained and strength testing algorithms were finalized, quality of life data collection forms were chosen, and the endocrinology tests to be performed were chosen after consultation with the appropriate collaborators. The statistical plan was completed and the regulatory and financial agreements with participating institutions were negotiated to near final form. Finally, the clinical protocol was completed and submitted to the IRB. Preliminary commitment for drug supply was also obtained. However, before final IRB protocol approval was received and before drug supply was finalized, we learned that the clinical trial grant was not selected for funding.

Without such funding, the clinical trial had to be put on hold. To address peer review concerns, we have initiated a phase I protocol of androgen replacement in order to assess safety concerns. We have also initiated additional discussions with basic science collaborators in order to more carefully select the patient population on the basis of molecular markers. This could serve to enrich the patient population for patients most likely to experience benefit from the therapy, which would make the clinical trial more compatible with the described preclinical data.

With these addendums, we hope to submit the application again either to the DOD or to another funding organization.

Key Research Accomplishments: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.

Reportable Outcomes: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.

Conclusions: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.

References: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.

Appendices: Not Applicable.
This grant was to fund planning activities for a clinical trial, and planning activities to submit a clinical trial grant to the DOD. This was accomplished.